IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

INDIVIOR INC. and INDIVIOR UK LIMITED, Plaintiffs, v. DR. REDDY'S LABORATORIES S.A. and DR. REDDY'S LABORATORIES, INC., Defendants.	Civil Action No. 2:17-cv-07111

FIRST AMENDED COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Indivior Inc. (formerly known as Reckitt Benckiser Pharmaceuticals Inc.) ("Indivior") and Indivior UK Limited (formerly known as RB Pharmaceuticals Limited) ("Indivior UK"), (collectively, "Plaintiffs") file this Complaint against Defendants Dr. Reddy's Laboratories S.A. and Dr. Reddy's Laboratories, Inc. (collectively "DRL" or "Defendants") and allege as follows:

NATURE OF THE ACTION

1. This is an action for patent infringement arising under the Food and Drug Laws and Patent Laws of the United States, Titles 21 and 35 of the United States Code, respectively, arising from DRL's Abbreviated New Drug Application ("ANDA") to the Food and Drug Administration ("FDA") seeking approval to manufacture, use, and sell a generic version of Plaintiffs' Suboxone® sublingual film prior to the expiration of United States Patent No. 9,687,454 ("the '454 patent" or "the patent-in-suit").

THE PARTIES

2. Plaintiff Indivior is a Delaware corporation having a principal place of business at 10710 Midlothian Turnpike, Suite 430, Richmond, Virginia.

3. Plaintiff Indivior UK Limited is a United Kingdom corporation having a principal place of business at 103-105 Bath Road, Slough, UK.

4. On information and belief, Dr. Reddy's Laboratories S.A. is a corporation organized and existing under the laws of Switzerland, having a place of business at Elisabethenanlage 11, CH-4051 Basel, Switzerland.

5. On information and belief, Dr. Reddy's Laboratories, Inc. is a New Jersey corporation having a principal place of business at 107 College Road East, Princeton, NJ 08540.

6. On information and belief, Dr. Reddy's Laboratories, Inc. is a wholly owned subsidiary of Dr. Reddy's Laboratories S.A.

7. On information and belief, Dr. Reddy's Laboratories, Inc. is controlled by Dr. Reddy's Laboratories S.A.

8. On information and belief, Dr. Reddy's Laboratories, Inc. is the U.S. agent of Dr. Reddy's Laboratories S.A.

9. On information and belief, both Dr. Reddy's Laboratories S.A. and Dr. Reddy's Laboratories, Inc. collaborated and/or acted in concert in the maintenance of ANDA Nos. 205299 and 205806.

JURISDICTION AND VENUE

10. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

11. On information and belief, Defendants are in the business of, *inter alia*, developing, manufacturing, obtaining regulatory approval, marketing, selling, and distributing generic copies of branded pharmaceutical products in New Jersey and throughout the United States.

12. This Court has personal jurisdiction over Defendants because of, *inter alia*, Dr. Reddy's Laboratories, Inc.'s incorporation in New Jersey; Dr. Reddy's Laboratories, Inc.'s

principal place of business in New Jersey; Defendants' continuous and systematic contacts with corporate entities within this judicial district; Defendants' purposeful availment of the benefits and protections of the laws of New Jersey; and Defendants' marketing and sales activities in this judicial district, including, but not limited to, the substantial, continuous, and systematic distribution, marketing, and/or sales of generic pharmaceutical products to residents of this judicial district.

13. On information and belief, Dr. Reddy's Laboratories, Inc. holds a license in the State of New Jersey as a "manufacturer and wholesaler" of drugs, with License No. 5002312. On information and belief, Dr. Reddy's Laboratories, Inc. employs people throughout the State of New Jersey, including at least the following location: 107 College Road East, Princeton, NJ 08540. On information and belief, Dr. Reddy's Laboratories, Inc. conducts business in this Judicial District and purposefully avails itself of this forum by, among other things, making, shipping, using, offering to sell or selling, or causing others to use, offer to sell, or sell, pharmaceutical products in the State of New Jersey and deriving revenue from such activities. Also, on information and belief, Dr. Reddy's Laboratories, Inc. has customers in the State of New Jersey.

14. Venue is proper in this District under 28 U.S.C. §§ 1391 and 1400.

THE PATENT-IN-SUIT

15. Plaintiff Indivior UK is the lawful owner of the '454 patent, and Plaintiff Indivior is an exclusive licensee of the '454 patent. The '454 patent, entitled "Sublingual and Buccal Film Compositions," was duly and legally issued on June 27, 2017, naming Garry L. Myers, Samuel D. Hilbert, Bill J. Boone, Beuford Arlie Bogue, Pradeep Sanghvi, and Madhusudan Hariharan as inventors. A true copy of the '454 patent is attached hereto as Exhibit A.

SUBOXONE® SUBLINGUAL FILM

16. Plaintiff Indivior is the holder of New Drug Application ("NDA") No. 22-410 for Suboxone® (buprenorphine hydrochloride and naloxone hydrochloride) sublingual film.

17. On August 30, 2010, the FDA approved NDA No. 22-410 for the manufacture, marketing, and sale of Suboxone® sublingual film for the treatment of opioid dependence. Plaintiff Indivior has sold Suboxone® sublingual film under NDA No. 22-410 since its approval.

18. The '454 patent is listed in the FDA's *Approved Drug Products with Therapeutic Equivalence Evaluations* (the "Orange Book") as covering Suboxone® sublingual film.

THE DRUG APPROVAL PROCESS

19. In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act, commonly known as the "Hatch-Waxman Act" and codified at 21 U.S.C. § 355. The Hatch-Waxman Act was intended to balance two important public policy goals. First, Congress wanted to ensure that innovator drug manufacturers would have meaningful patent protection and a period of marketing exclusivity to enable them to recoup their investments in the development of valuable new drugs. Second, Congress sought to ensure that, once the patent protection and marketing exclusivity for these drugs expire, consumers would benefit from the availability of lower priced generic versions of approved drugs.

20. Under 21 U.S.C. § 355(b)(1), the innovator drug manufacturer and NDA applicant is required to submit extensive testing and safety information concerning the drug. In addition, the NDA applicant must submit information on "any patent which claims the drug for which the applicant submitted the application or which claims a method of using such drug and with respect to which a claim of patent infringement could reasonably be asserted." Once the NDA is approved, the FDA lists this patent information in the Orange Book.

21. In contrast, the Hatch-Waxman Act allows ANDA applicants to obtain FDA approval for generic versions of previously-approved drugs without having to repeat the extensive testing required for a new drug application. Under 21 U.S.C. § 355(j), ANDA applicants can rely on FDA's previous findings of safety and efficacy for an approved drug product, if they demonstrate, among other things, that the generic drug is bioequivalent to the previously-approved drug.

22. Under 21 U.S.C. § 355(j)(2)(A)(vii), the ANDA must also include one of the following four certifications with respect to each of the patents listed in the Orange Book for the previously-approved drug product: (i) that the patent information has not been filed (a "Paragraph I" certification); (ii) that the patent has expired (a "Paragraph II" certification); (iii) that the patent will expire on a specific date, and the generic will stay off the market until that date (a "Paragraph III" certification); or (iv) that the "patent is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted" (a "Paragraph IV" certification).

DEFENDANTS' INFRINGING GENERIC PRODUCT

23. Non-party Teva Pharmaceuticals USA, Inc. ("Teva") submitted ANDA Nos. 205299, concerning Buprenorphine and Naloxone Sublingual Film, 2 mg/0.5 mg and 8 mg/2 mg, and 205806, concerning Buprenorphine and Naloxone Sublingual Film, 4 mg/1 mg and 12 mg/3 mg, to the FDA under 21 U.S.C. § 355(j), seeking approval to engage in commercial manufacture, use, and/or sale of a generic product before expiration of the patent-in-suit.

24. Teva transferred ownership of ANDA Nos. 205299 and 205806 to Defendants effective August 5, 2016. Order to Substitute Defendants, *Reckitt Benckiser Pharmaceuticals Inc. et al v. Dr. Reddy's Laboratories S.A., et al.*, No. 14-1451-RGA, (D.Del. Sept. 22, 2016), ECF No. 203.

25. Defendants acquired and have maintained ANDA Nos. 205299 and 205806 in the FDA under 21 U.S.C. § 355(j), seeking approval to engage in commercial manufacture, use, and/or sale of Defendants' generic product before expiration of the patent-in-suit.

26. ANDA Nos. 205299 and 205806 refer to and rely on Plaintiffs' NDA for Suboxone® sublingual film and purport to contain data showing bioequivalence of Defendants' generic product with Suboxone® sublingual film.

DRL'S PARAGRAPH IV NOTICE

27. After filing the Complaint on September 14, 2017 (Complaint, ECF No. 1), Plaintiffs received two Notification Letters from both Defendants no earlier than September 22, 2017. The Notification Letters concerned ANDA Nos. 205299, Buprenorphine and Naloxone Sublingual Film, 2 mg/0.5 mg and 8 mg/2 mg, and 205806, Buprenorphine and Naloxone Sublingual Film, 4 mg/1 mg and 12 mg/3 mg. Each of the Notification Letters contained Paragraph IV certifications alleging that the '454 patent is invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the generic product proposed in the ANDAs.

28. The Notification Letters further state that DRL submitted ANDA Nos. 205299 and 205806 to the FDA under 21 U.S.C. § 355(j), seeking approval to engage in commercial manufacture, use, and/or sale of DRL's generic product before expiration of the patent-in-suit. On information and belief, ANDA Nos. 205299 and 205806 concern dosages of Defendants' generic product and refer to and rely on Plaintiff Indivior's NDA for Suboxone® sublingual film and purport to contain data showing bioequivalence of DRL's generic product with Suboxone® sublingual film.

29. Plaintiffs amended this action within 45 days of receiving the Notification Letters.

COUNT 1: Infringement of the '454 Patent Under 35 U.S.C. § 271(e)(2)

30. On information and belief, Defendants' generic product is covered by one or more claims of the '454 patent.

31. By maintaining ANDA Nos. 205299 and 205806 filed by Teva under 21 U.S.C. § 355(j) for the purposes of obtaining approval to engage in the commercial manufacture, use, and/or sale of Defendants' generic product prior to the expiration of the '454 patent, Defendants committed an act of infringement of the '454 patent under 35 U.S.C. § 271(e)(2).

32. Plaintiffs are entitled to the relief provided by 35 U.S.C. § 271(e)(4), including, *inter alia*, an order of this Court that the FDA set the effective date of approval for ANDA Nos. 205299 and 205806 to be a date which is not any earlier than the expiration date of the '454 patent, including any extensions of that date.

COUNT 2: Declaratory Judgment of Infringement of the '454 Patent Under 35 U.S.C. § 271

33. On information and belief, unless enjoined by this Court, Defendants plan and intend to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Defendants' generic product immediately following approval of ANDA Nos. 205299 and 205806.

34. On information and belief, Defendants' manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Defendants' generic product before the expiration of the '454 patent would infringe one or more claims of the '454 patent under 35 U.S.C. § 271.

35. The acts of infringement by Defendants set forth above will cause Plaintiffs irreparable harm for which they have no adequate remedy at law, and those acts will continue unless enjoined by this Court.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request that this Court enter:

A. A judgment that Defendants have infringed the '454 patent under 35 U.S.C. § 271(e)(2) by maintaining ANDA Nos. 205299 and 205806;

B. A declaratory judgment that Defendants' manufacture, use, offer for sale, sale, marketing, distribution, and/or importation within the United States of Defendants' generic product would infringe the '454 patent under 35 U.S.C. § 271;

C. Preliminary and permanent injunctions, restraining and enjoining Defendants, their officers, agents, attorneys, affiliates, divisions, successors and employees, and those acting in privity or concert with them, from engaging in, causing, or inducing the commercial manufacture, use, offer to sell, or sale within the United States, or importation into the United States, of drugs and formulations, or from inducing and/or encouraging the use of methods, claimed in the patent-in-suit;

D. An order that the effective date of any approval of ANDA Nos. 205299 and 205806 be a date that is not earlier than the expiration of the patent-in-suit, including any extensions thereof and any later expiration of exclusivity associated with the '454 patent;

E. A judgment and order finding that this is an exceptional case within the meaning of 35 U.S.C. § 285 and awarding to Plaintiffs their reasonable attorneys' fees;

F. A judgment granting Plaintiffs compensatory damages in an amount to be determined at trial including both pre-judgment and post-judgment interest if Defendants commercially manufacture, use, offer to sell, or sell in the United States, or import into the United States, Defendants' generic product before the expiration of the patent-in-suit, including any extensions; and

G. Any and all other relief as the Court deems just and proper.

Dated: November 6, 2017

TROUTMAN SANDERS LLP

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